REMARKS/ARGUMENTS

Responsive to the Office Action dated August 10, 2010, Applicant appreciates the Examiner's time and courtesy in granting Applicant a telephonic interview on October 12, 2010 to discuss the instant application. In view of the Examiner's comments, in this Amendment, Claims 27 and 37 have been amended and Claims 36 and 43 have been canceled. Claims 14 and 15 were previously withdrawn. Accordingly, Claims 23 and 27-35 and 37-42 remain pending for prosecution with Claims 27 and 37 being independent. To further aid in understanding the present invention, Applicant has attached hereto a photograph of a bovine muzzle with the nasal plane and nostrils identified.

I. CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 36 and 43 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicant has canceled Claims 36 and 43 thereby rendering this rejection moot.

Claims 23 and 36-43 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the Examiner's suggestions, Applicant has amended Claims 23, 37, 39 and 41. Claims 36 and 43 have been canceled. Applicant therefore respectfully requests reconsideration and withdrawal of this rejection.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

A. Obviousness

When determining the question of obviousness, underlying factual questions are presented which include: (1) the scope and content of the prior art; (2) the level of ordinary skill

in the art at the time of the invention; (3) objective evidence of nonobviousness; and (4) the differences between the prior art and the claimed subject matter. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). Moreover, with regard to the last prong of the *Graham* inquiry, "[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit." KSR International v. Teleflex Inc., 127 U.S. 1727 (2007).

Applicant does not contest that the references that have been cited and relied on by the Examiner have at least marginal pertinence to the particular problem(s) solved by the present invention in that the references disclose methods for treating or vaccinating animals. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 USPQ 8781, 8786 (Fed. Cir. 1983).

The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art. Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986). The level of ordinary skill in the art of veterinary compositions and methods for treating animals may be determined by looking to the references of record. In re GPAC, Inc., 57 F.3d 1573, 35 USPQ2d 1116 (Fed. Cir. 1995). The references of record in this case reveal that a moderate level of sophistication in the veterinary arts is associated with one of ordinary skill. Thus, Applicant submits that, as substantiated by the cited references, those with at least a bachelor's degree in chemistry or biochemistry or substantial experience in the veterinary industry or the like would most likely be a person with ordinary skill in this field of endeavor.

With respect to objective evidence of nonobviousness, Applicant re-asserts that the record supports the conclusion that there are long-felt but unsolved needs met by the present invention. A snapshot of the knowledge of a person skilled in the art at the time Applicant filed the patent application for the present invention is summarized in the October 4, 2002 article by Pfizer Global Research and Development entitled Pharmaceutical Challenges in Veterinary Product Development. This article was submitted to the USPTO and identified in the June 25, 2009 Supplemental Information Disclosure Statement. The above-referenced paper provides a "brief review of the animal health pharmaceutical product landscape," "highlights challenges and special consideration in veterinary drug delivery," and "identifies unmet needs in animal health along with recent advances" as the state of the art existed in October 2002. Tablets and injectables were identified as the two most common dosage forms in veterinary applications in 2002. Three major areas of drug delivery needs identified at the time of the Applicant's invention were: convenient delivery for companion animals, long-acting implants and injections, and dosing devices and needle-free injectors.

More specifically, the article identifies the following long-felt needs in a pharmaceutical or vaccine administration method: reducing human and food safety concerns due to "injection site toleration;" a "no needles" method being a high priority need in animal health, particularly in livestock pharmaceuticals and vaccines; and alleviating the risk of injury using traditional methods that are laborious and require animal restraint. This article, however, fails to identify the Applicant's claimed method of applying a prophylactic composition to the exterior of the bovine animal's nasal plane between the nostrils and above the upper lip as a known administration in the art in its "state of the art" in pharmaceutical and vaccine administration to livestock summary. Moreover, this reference pointedly identifies unmet and long-felt needs in

the art at a time subsequent to the present application's filing date. Applicant's invention, therefore, is non-obvious because it satisfies many of the unmet and long-felt needs in the art identified at the time of Applicant's invention.

In particular, the present invention is directed to the particular problem of providing a method for treating bovine with a veterinary composition that does not require animal restraint, eliminates the use of needles, administers the composition to the animal's mucosal membranes, avoids close physical contact with the animal, and provides a visual indicator of vaccination. The present invention does not require a handler to restrain the animal or fight the animal to restrain its head thereby minimizing stress on the animal. Further, the reduced degree of contact between man and animal provided by the present invention greatly reduces risk of injury to both. Additional benefits of the present invention over the prior art include eliminating the use of needles thereby eliminating the risk of spreading blood and skin borne diseases from animal to animal, injection pain and broken needles in edible tissues, as well as avoiding site reactions which may result in the loss of saleable tissues due to injection site lesions showing up in the final food product.

The present invention also uses the natural route of infection in order to provide a dual system of immune processing through the oral and/or nasal mucosa while minimizing the physical contact between man and animal. The present invention is also cost effective in that it requires minimum reformulation and does not require any new technology for use in connection with respiratory viruses and/or attenuated bacteria. Finally, the present invention allows handlers of large groups of bovine animals to visually identify animals that have already been administered the prophylactic composition. The post-application identifier increases administration efficiency and prevents an animal from being given two doses of the prophylactic

composition and also allows the handlers to visually identify animals that have not been administered the prophylactic composition. In summary, the present application is directed to a method of treating bovine that includes applying a single effective dose of a prophylactic composition directly to the exterior of the bovine animal's nasal plane between the nostrils and above the upper lip wherein the animal distributes the effective dose into its oral and/or nasal cavities to contact the oral and/or nasal mucosal membranes with its tongue and the method also includes a post-application identifier. These features represent a solution to long felt needs in the art that were not met by the known prior art.

Finally, prima facie obviousness requires that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references. This motivation-suggestion-teaching test informs the Graham analysis. "To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references," there must be "some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct." In re Kahn, (Fed. Cir. 2006). The KSR International decision by the Supreme Court has not eliminated the motivation-suggestion-teaching test to determine whether prior art references have been properly combined. Rather, in addition to the motivation-suggestion-teaching test, the Court discussed that combinations of known technology that are "expected" may not be patentable. Stated in the affirmative, therefore, combinations are nonobvious and patentable if unexpected. In the present application, no single prior art reference nor any combination thereof meets the claimed limitations or provides an expectation of Applicant's claimed invention.

B. Rejection of Claims 27, 28, 31-33, 35-40 and 43 over Gallili in view of Hasker and as evidenced by Madey.

Claims 27, 28, 31-33, 35-40 and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gallili (US 6,541,001 B1) in view of Hasker et al. and as evidenced by Madey, Judith. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of these rejections.

Applicants respectfully traverses the assertions that the Gallili, Hasker and Madey references, alone or as combined, teach or suggest all of Applicant's claim limitations or that the claimed limitations of the present invention are the expected result when these references are combined. Applicant's method of administration of prophylactic compositions is not rendered obvious by the asserted combination for the reasons discussed hereinbelow.

Gallili does not teach applying at least a single effective dose of the prophylactic composition directly to the exterior of the exterior of the bovine's nasal plane between the nostrils and above the upper lip. Gallili teaches that a dose of a prophylactic composition can be administered via a whole body spray applied to the exterior of the animal. This application method teaches away from applying a single effective dose directly to the exterior of the nasal plane of the bovine animal. While some of the spray may incidentally hit the muzzle during the whole body spray, the single effective dose applied in Gallili's whole body spray is inherently distributed over the animal's entire body—not applied directly to the exterior of the nasal plane. Accordingly, administering a prophylactic composition by spraying it over the whole body of an animal, as taught in Gallili, and applying a single effective dose directly to the exterior of the animal's nasal plane e as claimed in the present invention are mutually exclusive.

Moreover, Gallili does not teach or suggest a reliance on the tongue to distribute the single effective dose. In fact, the word "tongue" is not present in the Gallili disclosure. As a result, Gallili's disclosure fails to teach, suggest or motivate a person skilled in the art to apply at least a single effective dose directly to the exterior of a bovine animal's nasal plane wherein the bovine animal distributes the single effective dose into its oral and/or nasal cavities to contact the oral and/or nasal mucosa when it cleans its nasal plane with its tongue. Similarly, Hasker and Madey both fail to teach or suggest the application of at least a single effective dose directly to the exterior of a bovine animal's nasal plane wherein the bovine animal distributes the single effective dose into its oral and/or nasal cavities to contact the oral and/or nasal mucosa when it cleans its nasal plane with its tongue. Accordingly, Gallili, Hasker and Madey, individually and in combination, fail to teach, suggest or motivate a person skilled in the art to directly apply at least a single effective dose to the exterior of an animal's nasal plane between the nostrils and above the upper lip wherein the bovine animal distributes the single effective dose into its oral and/or nasal cavities to contact the oral and/or nasal mucosa when it cleans its nasal plane with its tongue.

C. Rejection of Claim 23 over Gallili and Hasker as evidenced by Madey.

Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Gallili and Hasker as evidenced by Madey. Per the arguments presented above in Section B, the asserted combination does not establish a prima facie case of obviousness for independent claims 27 or 37 and the claims depending therefrom. In addition, the cited references, alone or in combination do not teach, suggest, or motivate the combination asserted in the Office Action. None of the references teach directly applying at least a single effective dose of such a prophylactic or immunizing composition to the exterior of the nasal plane between the nostrils of

a bovine animal wherein the animal distributes the single effective dose to the animal's oral and nasal cavities with its tongue. Therefore, claim 23 of the present invention is nonobvious.

D. Rejection of Claims 34 and 38 over Gallili and Hasker as evidenced by Madey and further in view of Demello.

Claims 34 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable Gallili, Hasker and Madey further in view of Demello et al. (US 5,846,830). For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Applicant respectfully traverses the assertion that the cited references, when combined, teach or suggest all of Applicant's claim limitations or that the claimed limitations of the present invention is the expected result of this combination. Per the arguments presented above in Section B, the combination of Gallili, Hasker and Madey does not establish a prima facie case of obviousness for independent claims 27 or 37 and the claims depending therefrom. Moreover, Demello does not teach directly applying at least a single effective dose of a prophylactic composition to the exterior of the nasal plane of a bovine animal wherein the animal distributes the single effective dose to the animal's oral and/or nasal cavities with its tongue. Thus, Gallili, Hasker, Madey, and Demello, alone or in combination, do not teach or suggest every claimed limitation of the present invention, and do not teach or suggest to a person skilled in the art that the present invention is the expected result of the combination as asserted in the Office Action. Accordingly, Applicant's claims 34 and 38 are nonobvious.

E. Rejection of Claims 29-30 and 41-42 over Gallili, Hasker, Madey and further in view of Callaghan.

Claims 29-30 and 41-42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gallili, Hasker and Madey in view of Callaghan et al. (US 6, 541,001 B1). Applicant

respectfully traverses the assertion that the cited references, when combined, teach or suggest all of Applicant's claimed limitations or that the claimed limitations of the present invention are the expected result of such a combination. Applicant's claimed invention, directed to a method of administration of prophylactic compositions to bovine animals, is not rendered obvious by the asserted combination for the same reasons as set forth above.

III. CONCLUSION

Applicant respectfully submits the claims and the application are in condition for allowance and such is courteously solicited. If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard. Should any fees be necessitated by this response, the Commissioner is hereby authorized to deduct such fees from Deposit Account No. 11-0160.

Respectfully submitted,

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